

CONDITION: CORNEAL REFRACTIVE SURGERY (ICD9 V 802A and V802B)

This policy is designed to establish a medical process by which initial applicants and rated aviation personnel may obtain an exception to policy or waiver for the voluntary refractive surgery procedures laser in-situ keratomileusis (LASIK) or photorefractive keratectomy (PRK) in order to improve visual acuity. It is not the intent of this policy to obligate any resources not readily available.

AEROMEDICAL CONCERNS:

Corneal refractive surgery is a surgical treatment for the correction of refractive error (myopia, hyperopia or astigmatism). There are presently four surgical procedures: Radial Keratotomy (RK), Photorefractive Keratectomy (PRK), Laser in Situ Keratomileusis (LASIK), and Intra-Corneal Ring Implants (ICR). Civilian eye specialists are performing all procedures, but LASIK is currently the most common. PRK and LASIK have similar results in uncorrected visual acuity improvement at 6 months but differ in technique and immediate post-operative results.

RK involves a radial pattern of surgical incisions in the cornea. Military ophthalmologists have determined that RK does not produce stable visual correction in operational environments and seriously weakens the integrity of the eye. This procedure is not waiverable for the Army or Army aviation.

PRK involves removing the corneal epithelium and then applying a series of fine laser ablations to re-sculpt the cornea. PRK lases through the basement membrane of the surgically removed epithelium and sculpts the corneal stroma to an average depth of 70 microns (typical corneal depth 550 microns). During the first weeks after the procedure the surface epithelium must repopulate the corneal surface and during this period there is discomfort and fluctuating vision. Some studies suggest there is increased risk of haze at the treated interface with increased ultraviolet exposure due to the destruction of the basement membrane even years later. LASEK (Laser Subepithelial Keratomileusis) is considered a variant of PRK under this policy.

LASIK also uses the laser to sculpt the corneal stroma to a 70 micron depth but it differs from PRK in that a surgical blade is used to create a hinged flap approximately 160 microns thick. This flap is laid back and the stromal bed treated with the laser. When the flap is repositioned, vision is generally excellent immediately and there is no significant discomfort. LASIK has the theoretic risk of displacement of this flap, however preliminary basic science studies and clinical studies in the Airborne and Ranger student populations as well as the experience in the civilian population does not seem to support this concern as being of any operational or clinical relevance. The incidence of displacement of the flap is extremely low and the risk decreases with time.

ICR involves creating two channels in the corneal stroma and inserting plastic arcs which expand the peripheral cornea and flatten the central cornea resulting in a decrease in myopia. It is an incisional procedure and is not waivable for the Army or Army aviation.

ADVANTAGES: Prior to FDA approval, extensive clinical studies were performed to assess PRK safety and efficacy. Ten year follow-up data is available from some of the studies conducted. More recently, the pool of those who may be eligible for treatment has expanded to include more severe forms of myopia, as well as hyperopia and astigmatism.

Potentially 80-90 percent of people who require glasses for distance vision may be eligible for PRK. It is an effective procedure, with up to 95 percent of treated patients not needing distance glasses to achieve 20/40 vision or better. Approximately 75 percent of patients achieve 20/20 vision. The results may not be quite as good among patients with more extreme forms of myopia, hyperopia or astigmatism. The visual improvement appears to remain stable after healing from the surgery. Developing wavefront technology holds the promise of custom corneal ablations to produce “super-vision” (20/10- the theoretic anatomic limit of vision- which statistically occurs naturally more frequently in aviators attending the Navy’s Top Gun Program).

DISADVANTAGES: As with any surgical procedure, there may be side effects and complications. Most of these are short term, and resolve within a few weeks following the procedure. But, some may take longer to resolve, or in a small percentage of cases, could be permanent. These include decreased night vision, glare sensitivity, and/or worsening of the pre-operation best vision due to scar formation and other effects of the healing process. With both PRK and LASIK, it is not uncommon for up to 10% of patients to require retreatment with the laser to ‘fine tune’ the desired corrective effects of the procedure.

While the final visual acuity results are identical for PRK and LASIK, there is a longer recovery time following PRK. Finally, though it is not anticipated that adverse complications will occur 10 or more years after the surgery, there is no data available to determine what, if any, changes may develop later in life.

RESPONSIBILITIES:

Flight Surgeons/APAs: Flight Surgeons/APAs will initiate requests for waiver or exception to policy. Flight Surgeons will ensure aviation personnel who have a waiver under the Corneal Refractive Surgery APL will complete all required evaluations during the course of their career.

US Army Aeromedical Research Laboratory (USAARL): USAARL will assist USAAMA in review of exception to policy or waiver requests submitted for future or current aviation personnel and will provide recommendations to USAAMA. USAARL

will administer the visual performance battery to applicable categories of personnel, as described below. USAARL will provide USAAMA with the data obtained for entry into the AEDR.

WAIVERS:

All forms of corneal surgery are disqualifying for aviation duty.

Initial Applicants:

Class 1A/1W: Applicants undergoing PRK may be considered for exception to policy on a case by case basis provided information required as listed below is submitted. Applicants undergoing LASIK may be considered for an exception to policy only as part of the USAARL research protocol "Evaluation of Refractive Surgery for Army Aviation."

Class 2: Applicants undergoing PRK may be considered for waiver, but applicants undergoing LASIK may only be considered for waiver as part of the USAARL research protocol "Operational Assessment of Refractive Surgery for Army Aviation."

Class 2F, 3,4: Applicants may be considered for waiver for PRK or LASIK on a case-by-case basis provided the information required below is submitted.

Rated Aviation Personnel:

Personnel undergoing refractive surgery must receive authorization from their commanding officer prior to the procedure. Commanders should be advised that the procedures have a six to twelve week recovery period before aviation duties can be resumed (Appendix 1).

Class 2: Aviators undergoing ONLY PRK may be considered for waiver on a case-by-case basis. Information required is listed below. Individuals desiring LASIK may only obtain the surgery and continued follow-up as part of a USAARL research protocol.

Class, 2F, 3 and 4: Individuals can be considered for waiver for PRK or LASIK on a case-by-case basis.

INFORMATION REQUIRED:

- Detailed pre-operative, operative, and post-operative refractive surgery follow-up records (Appendix 2). The post-operative information must include the following:
 1. Manifest refraction (at least 2 refractions one month apart to establish stability)
 2. Visual acuity (best corrected 20/20 each eye)
 3. Slit lamp examination (no residual haze or other complications)
 4. Corneal topography (post-operative topography map)
 5. Contrast Sensitivity (5% contrast using the Precision Vision backlit chart)
- Document that at least 3 months (for initial applicants) or 6 weeks (for current aviation personnel) have elapsed since surgery or re-treatment and evidence of stable refractive error is demonstrated by two separate examinations performed at least one month apart.
- Initial Class 1W/1A/2 or Class 2 rated aviation personnel undergoing LASIK must be accepted into an Army approved corneal refractive surgery study protocol.

FOLLOW-UP: The every five year comprehensive flying duty medical examination (FDME) must include an optometry/ophtalmology consult for completion of a slitlamp examination of the cornea, manifest refraction, corrected visual acuity and 5% contrast sensitivity test. The 5% contrast test is not required for follow-up for classes 2F, 3, and 4 but will be completed if available. A contrast sensitivity test is required for class 2 personnel. The preferred test is the 5% contrast test, however the following tests may be submitted in lieu of the 5% contrast test:

1. BVAT low contrast acuity (set on 5%)
2. Bailey-Lovie 10% low contrast acuity test
3. Pelli-Robson Contrast Sensitivity Test
4. Small Letter Contrast Test
5. VisTech or FACT Contrast Sensitivity Test

TREATMENT: Per appropriate surgical protocols.

DISCUSSION:

Corneal refractive surgery will optimally result in less optometric support before and during deployment to Stability and Support Operations as well as combat operations. There is a significant medical logistics “footprint” of combat health support activities providing corrective lenses and protective mask inserts that may be lessened. This is especially important in current rapid deployment, high op tempo environments. Corneal refractive surgery is an additional benefit in the continuous development of new man-machine interfaced weapons based on routinely updated detailed vision parameters. This is especially important for increasingly complex flight environments where corrective lenses would be a hindrance.

Advantages and disadvantages for both LASIK and PRK have been identified and will be further elucidated by the continuing research. In order to do this, there are two study arms in the USAARL programs, one looking at accessions into aviation and one looking at active aviation personnel who desire the procedure. The accession arm will follow subjects who have had LASIK and who meet criteria specified in the applicable protocol. The other arm will include trained aviation personnel upon whom LASIK has been performed at the US Army Aeromedical Center or a DOD medical treatment facility (IAW AR 40-3, Chapter 2-11). USAARL will be responsible for providing study results and any required documentation to the Department of Defense Accessions Medical Standards Analysis and Research Activity (ASMARA) at CHPPM.

APPENDIX 1. Aviation Commander's Authorization

APPENDIX 2. Medical Release and Checklist for Eye Care Provider

Appendix 1

Aviation Commander's Authorization

Memorandum to: Unit Flight Surgeon

CC: Ophthalmology, Refractive Surgeon

Subject: Authorization for Aircrew members to receive refractive surgery under the Aeromedical Policy Letter for Refractive Surgery and the Corneal Refractive Surgery Surveillance Program.

1. _____, SSN _____ is authorized to receive refractive surgery per the guidance outlined in the Aeromedical Policy Letter: Corneal Refractive Surgery/

2. This authorization is based on the following understandings:

a. This authorization does not constitute a medical waiver; it only authorizes the individual to have refractive surgery. The individual will be DNIF for at least 6 weeks and possibly up to 12 weeks. The medical waiver request will be submitted to USAAMA upon receipt of information from the flight surgeon as to the successful outcome of the individual's surgical procedure. USAAMA will determine if the individual's meets the medical waiver requirements when the applicant's eyes and vision meet and retain FDME standards and all requirements for waiver have been met.

b. Two to 3 of 1000 eyes (0.2 to 0.3%) will not recover 20/20 best-corrected vision after refractive surgery. Individuals who fall in this category will be evaluated by USAAMA to determine whether a waiver to continue on flight status may be issued. Although slight, there is a possibility the individual may lose his/her flight status in the case of significant visual loss that cannot be resolved.

c. Questions about the study may be directed to USAARL at 334-255-6810, about waivers to USAAMA at 334-255-7430, and about refractive surgery to the local eyecare provider.

d. A copy of this correspondence will be kept on file in the local flight surgeon's office.

3. POC is the undersigned at _____.

Commander's Signature Block

Appendix 2

Request for Release of Medical Records (completed by waiver applicant and provided to eye care provider for completion)

From: (enter your information)

Date:

To: (enter eye clinic information)

Subject: Request for records related to refractive surgery procedure

1. Request a copy of records pertaining to my refractive surgery be provided to:

(enter unit flight surgeon information and address)

2. The following information is needed (see attached Checklist for Eye Care Provider):

Date of procedure

Type of procedure (PRK or LASIK)

Type of laser (brand name)

Ablation parameters (size of ablation zone, microns of tissue removed, number of pulses, if available)

Amount of correction (sphere, cylinder and axis)

Pre-operative refraction and date (specify manifest or cycloplegic)

Follow-up refractions with visual acuities and dates (most current refraction and as many postoperative refractions as possible)

Slitlamp assessment of cornea (presence or absence of haze or other complications)

Latest **post-operative** corneal topography (instantaneous or tangential corneal maps)

Contrast Sensitivity (preferred test is the 5% low contrast letter acuity)

Typed or Printed Name

Signature

Study applicant

Last name: _____ First name: _____ Middle initial: _____

Date of Birth _____ Contact Tel. #: _____

Eye Care Provider

Name: _____ Date of report: _____

Clinic address & telephone: _____

Specific procedure detailsDate of Procedure: _____ Type (circle one): PRK or LASIK
Laser Used: (manufacturer) _____ (model #) _____

Ablation parameters (Complete below, or if available, attach copies of laser records)

OD: Size of ablation: _____ mm Tissue removed: _____ microns # of Pulses: _____

OS: Size of ablation: _____ mm Tissue removed: _____ microns # of Pulses: _____

Amount of correction programmed into laser

OD: _____ OS: _____

Pre-operative Refraction

OD: _____ OS: _____

Did the applicant require any enhancement procedures? Yes _____ No _____
(If yes, please provide details, as above)**Follow-up examinations** (include most recent and 2 prior examinations)

Date	Refraction	Visual acuity	Corneal haze* (circle one)
	OD _____ OS _____	OD _____ OS _____	OD 0 1 2 3 4 OS 0 1 2 3 4
	OD _____ OS _____	OD _____ OS _____	OD 0 1 2 3 4 OS 0 1 2 3 4
	OD _____ OS _____	OD _____ OS _____	OD 0 1 2 3 4 OS 0 1 2 3 4

* Haze 0-4 scale. 0=no haze, 1=trace, 2=minimal, 3=moderate, 4=iris details obscured.

Corneal topography (include copy of most recent corneal topography using the TANGENTIAL or INSTANTANEOUS map display option)

Topographer used:

Manufacturer: _____

Model: _____

Date of topographies: _____

Contrast sensitivity (attach copy of results, if available)

Test Used:

Manufacturer: _____

Model: _____

Date of contrast test: _____

Test Conditions:

Room Lights ON (circle one)

Yes

No

Backlit Chart (circle one)

Yes

No

Distance to test _____ m

% Contrast (if letters) _____ %

Results:

OD _____

OS _____
